

### **REMARKS**

Applicant kindly thanks the Examiner for the Office action of August 11, 2004, in which claims 1-28 were rejected as obvious over several references. Applicant respectfully maintains that all claims as originally filed were allowable without amendment, but has amended claim 1 to incorporate original dependent claims 13, 15 and 16, without prejudice to filing one or more continuation applications covering original claims 1-28 and the non-elected claims. The specification has also been amended to supply the American Type Culture Collection (ATCC) accession numbers, as well as to clean up various minor issues. No new matter has been added to the application. As two deposits were made after the effective filing date of the application, a corroborating statement as required under 37 CFR Section 1.804(b) is being obtained from the inventor and will be forwarded promptly.

With the entry of the amendments herein, and consideration of the arguments regarding the references cited as well as the state of the art, it is respectfully maintained that the application is now in condition for allowance.

### **The Claimed Invention**

The present inventive fertilizer is a unique and patentable composition that departs from previous efforts to improve crop yields using animal manure-based fertilizers, while at the same time reducing the total nitrogen requirement of the plant. The key components of the compositions of the invention are decontaminated manure and an effective amount of *Bacillus* spores having the characteristics recited in Claim 1, as amended. It is important to note that these two components, in combination and as now claimed, are not taught or suggested in any of the references known to the inventor or cited by the examiner.

The decontaminated manure ingredient may be produced by composting animal manure, by chemical treatment, or combination of these methods. In any case, the important point regarding this ingredient is that the animal manure must be *decontaminated* as taught in the specification (see especially pages 15-17). As used in

the invention, "decontaminated" means the animal manure has a total microbial plate count per gram reduced by about 2-4 logs (100 to 10,000) compared with fresh, untreated (raw) manure. Furthermore, when manure with a microbial content below  $1 \times 10^6$  cfu/gram is employed, the fertilizer compositions of the invention will have *Bacillus* purity of greater than 90 percent. (page 16, lines 16-22).

Regarding the *Bacillus* spores, note that any *Bacillus* species that produces stable spores can be used in the invention (specification at page 15, lines 1-23). Preferred are those species and strains of *Bacillus* that are capable of exerting a positive effect on the microbial composition of the rhizosphere of the plant in question, especially those strains that produce significant increases in the population of Actinomycetes and nitrogen-fixing bacteria within a plant rhizosphere (specification at page 15, lines 15-23). Particular species and strains, as well combinations thereof, are recited explicitly in Claims 1 and 17-21, and functionally in claim 24.

As noted in the specification discussing the various experiments and examples, a unique synergism has been discovered between probiotic *Bacillus* bacteria and decontaminated manure. See paragraph bridging pages 16-17, where it is noted "Experiment #4 illustrates the unique synergism that exists between probiotic *Bacillus* bacteria and decontaminated manure, treated by the hypochlorite process of the present invention, when they are used separately and in combination in potato production; potato yields are significantly greater when the combination is used. It is apparent that nutrients contained in the decontaminated manure stimulate the growth of the *Bacillus* within the rhizosphere environment leading to increased potato yields."

#### **The Scope and Content of the Prior Art**

The prior art can be simplified into 3 categories: those references that either treat raw animal manure to make it more usable as a fertilizer or teach avoiding its use altogether; those references discussing the use of microorganisms, including *Bacillus*, for increasing plant yields, usually in aqueous mixture; and those references teaching the use of a mixture of raw manure and microorganisms. However, as will be seen, there is no motivation from these references to decontaminate manure, or to combine

decontaminated manure and *Bacillus* microbes into a patentable combination. Indeed, many of the references admit that animal manure is to be avoided altogether, or do not recognize that there exist some benefits to its use if properly decontaminated. The teaching and understanding of benefits of the combination of decontaminated animal manure and *Bacillus* spores only comes from a reading of the present application.

The primary references applied by the examiner are CN 1141279 (the CN abstract); EP 0149796 (EP); and U.S. Pat. No. 6,228,806 (Mehta). (While it is understood that the teaching of the prior art as a whole is to be considered, it is helpful first to characterize each reference on its own terms.)

The CN abstract discloses a “multi-element composite fertilizer” that includes “farm manure, chemical fertilizer and humic acid.” There is no indication of decontamination of the farm manure, or motivation to do so, nor suggestion to mix with *Bacillus* spores.

EP discloses (in its English abstract) a “fertilizer grain” consisting of “a solid (set) coating of ground primary rock, which encloses a moist mixture of bird and/or poultry excrements.....and a fermentation humus, the mixture containing microorganisms” and optional N-P-K and other nutrients. Page 4, line 5 of EP mentions *Bacillus megatherium* as one microorganism useful in the mixture. There is no teaching or suggestion of decontaminating the bird and/or poultry excrements, or motivation to do so, nor suggestion to mix with *Bacillus* spores. The problem to be solved appears to be that non-coated (non-encapsulated) fertilizers leach out of soil too quickly. This was mentioned in at least one other reference, and was discussed in a recently issued patent to Biovance Technologies, Inc., U.S. Pat. No. 6,709,481, at column 1, line 19, through column 2, line 4.

Mehta addresses the problem of an “imbalance in the microbial eco-system” in soils of plants treated with chemical pesticides, and mentions at column 1, line 21 that animal manure can be used to introduce useful microorganisms; however, use of animal manure is disfavored as it also contributes over time to a build up of toxic chemicals and/or toxic metals. Mehta’s solution to this problem is a fertilizer composition comprising: A) an inorganic fertilizer and/or an organic fertilizer which is free or

substantially free from toxic chemicals and toxic metals; and B) an effective quantity of beneficial microorganisms (including *Bacillus Subtillus*) that a) enhance plant growth and, where applicable, crop production, and/or b) control various types of pathogens in the soil, optionally in combination with nutrients selected to maintain the viability of the microorganisms and/or increase their population. (See column 1, lines 37-45.) Mehta teaches that organic fertilizers that are free or substantially free from toxic chemicals and/or metals that can be used as component A), either alone or in combination with an inorganic fertilizer, include processed animal body and vegetable products such as blood meal, cottonseed meal, ocean kelp meal, fish fertilizers such as fish emulsion, feather meal, and the like. There is again no teaching or suggestion of decontaminating animal manure, or motivation to do so, or suggestion to mix decontaminated animal manure with *Bacillus* spores. Indeed, Mehta seems to teach one of ordinary skill in the art to avoid animal manure due to its apparent build up of toxic chemicals and/or toxic metals in soil.

The secondary references applied by the examiner are not helpful in filling in the missing motivation to combine decontaminated manure with *Bacillus* spores. O'Donnell (U.S. Pat. No. 5,702,701) discloses a method of treating soil with a composition containing *Bacillus laterosporus strain BOD*, but lacks any discussion of a combination of manure, raw or decontaminated, with any *Bacillus* species. The sole example in the patent employs a mixture of water and the *Bacillus laterosporus strain BOD*.

Branly et al. (U.S. Pat. No. 6,232,270) discloses a composition containing an agriculturally effective active ingredient and an enhancer containing a culture of bacteria selected from the genus *Bacillus* or a soil bacterium in an amount sufficient to enhance the effectiveness of an agriculturally effective active ingredient applied simultaneously, before, or after application of the enhancer. (See column 3, lines 59-64.) The "agriculturally effective active ingredient" is detailed in columns 12 and 13. One will search in vain for mention of manure, raw or decontaminated. Branly et al. teach the use of plant growth enhancing agents, such as the gibberellin plant growth hormones; fungicides; herbicides, and insecticides as the agriculturally effective active ingredient.

Johnson et al. (U. S. Pat. No. 6,174,472) disclose process for forming soil enhancing pellets. The pellets comprise at least sixty percent composted sewer sludge,

up to forty percent cellulosic plant material and up to fifteen percent nutrient materials and chemicals for soil enhancement and plant nutrition (abstract). The sewer sludge can apparently contain animal excrement, and is decontaminated to remove mesophyllic bacteria by composting to an extent that it may be used as a soil enhancer as established by the Environmental Protection Agency. (See column 8, lines 16-30.) The composition is stated to include thermophilic bacteria, such as *Bacillus subtilis*. There is no teaching or suggestion of the combining of the decontaminated manure with further microorganisms, much less *Bacillus*, as in the present invention.

Moran et al. (U.S. Pat. No. 4,459,149) disclose processes for treating humus materials to obtain humus acids. Peats, mucks, soils, anaerobic sludges, lignites and other humus materials containing humic substances are slurried in the natural wet state with additional water at low pH to free humic acid from salts it may have formed in the natural state and to disperse the humic acid as a fine suspension in the water. The resulting slurry is then screened to remove coarse material such as stones, fibers and cellulosic materials that may be present, and the liquid phase comprising a dispersion of humic acid is settled or otherwise treated to remove heavy inorganic fines if present. The dispersion is then filtered to yield a relatively pure and dry filter cake, comprising crude humic acid. The humus material may be found in lignite and other minerals and soils, such as Leonardite.

Robinson (U.S. Pat. No. 4,743,287) discloses a fertilizer and method of making same wherein a complex humic acid fertilizer is formed from a mix of a select organic material, water, and measured amounts of major inorganic elements of nitrogen, phosphate, potash and sulfur. The constituents mixed in a sealed reactor system with a first material, usually an acid, are hydrolyzed by a drastic pH change, raising the mix temperature and pressure, and the mix is subsequently blended with a second material of an opposite pH to the first material, usually a base, reacting with the mix to provide a further temperature and pressure increase, to alter the pH to that of the finished fertilizer, which humic acid fertilizer is then dried and granulated or liquefied to a pumpable slurry.

Wilson (U.S. Pat. No. 6,312,492) discloses a process for treating animal manure, particularly poultry feces, with concentrated sulfuric acid.

Lamy et al. (U.S. Pat. No. 6,245,121) disclose that waste concentrates from physico-chemical liquid/solid separation steps and from reverse osmosis may be combined for the purpose of converting them into an organic soil improver and/or organic fertilizer by aerobic fermentation (or composting). An oxidizing agent may be used before ultrafiltration or microfiltration. The oxidizing agent used is generally chosen from the group formed by oxygen, oxygenated derivatives, especially peroxides (for example hydrogen peroxide or ozone), chlorine, chlorinated derivatives (for example, chlorine dioxide, sodium hypochlorite, calcium hypochlorite, potassium hypochlorite, sodium chlorite, sodium chlorate or eau de Javelle) and potassium permanganate.

Wasinger (U.S. Pat. No. 6,056,885) discloses a method and apparatus for using ozone to disinfect, decontaminate and deodorize animal manure. The invention contemplates injecting ozone gas into manure, while the manure is rotated on an auger in a sealed chamber. As a result of Wasinger's invention, the manure is disinfected, decontaminated, and deodorized, while nutrients in the manure and a neutral pH are maintained. It appears that all microbes in the raw manure are killed by this teaching.

WO 96/28400 discloses an aerobic, thermophilic, alkaline composting process for biodegrading waste products and producing byproducts useful for bioremediation of contaminated soil, and for agriculture fertilizer. The document only discloses using composting derived bacteria (including *Bacillus* that survive composting) and does not teach or suggest a composition comprising decontaminated manure and *Bacillus* wherein the concentration of *Bacillus* spores is within the ranges claimed in the present invention. The document does recognize the benefit of using certain strains of *Bacillus* "found as end products of this invention" (composting) to be prolific and rapidly populate, and to have enzymes for catalyzing a reaction between water, nutrients and contaminated substrates to provide biomass degradation. However, there is no recognition of the synergistic effect of decontaminated manure combined with *Bacillus* spores in the concentrations claimed herein in increasing the production of crop plants.

#### **Differences Between the Prior Art and the Claimed Invention**

The primary differences between the prior art as a whole and the invention claimed in Claim 1 of the present application are that, even if combined as the Examiner has in the Office action, there is lacking in the prior art 1) any motivation to combine decontaminated manure with *Bacillus* spores, and 2) a composition comprising the synergistic combination of decontaminated manure with *Bacillus* spores, where the *Bacillus* spores have the concentration now claimed and the properties evidenced thereby in the Examples presented in the specification. Applicant submits that the Experiments and Examples supplied in the specification are ample evidence of this synergism.

### **Claim Rejections**

Given the scope and content of the prior art and the differences between the art and the claimed invention, Applicant maintains that the Examiner has failed to make out a *prima facie* case of obviousness, either for the original claims, or for the now amended versions. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As stated In re Gordon 221 USPQ 1125-1127 (Fed. Cir. 1984) and reaffirmed in In re Mills, 16 USPQ 2d 1430, 1432 (Fed. Cir. 1990):

The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.

Utilizing these principals in the present situation, it can be seen that there is totally lacking in the combination of primary and secondary references taken as a whole:

1) any suggestion or hint of the desirability of a modification which would entail combining decontaminated manure with the *bacillus* spore species recited in

pending independent Claim 1 (and functionally in Claim 24) at the claimed concentrations;

2) any expectation of the extraordinary success that the combination of decontaminated manure and *bacillus* spore strains and concentrations recited in independent Claim 1, or having the functions recited in independent Claim 24, would evidence such efficacious effects on crops as evidenced in Applicant's test data; and

3) teaching or suggestion of *all* the claim limitations of pending independent Claims 1 and 24.

Accordingly, it is abundantly clear that no *prima facie* case of obviousness can be made and that the compositions defined in now pending Claims 1-6, 8-12, 14, and 17-27 are manifestly nonobvious in view of the prior art of record under 35 U.S.C § 103(a).

Assuming, *arguendo*, that the Examiner has presented a *prima facie* case of obviousness, Applicant offers the following remarks. First of all, it must be reiterated that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." ACS Hospital Systems, Inc. vs. Montefiore Hospital, 221 USPQ 929, 933 (Fed. Cir. 1984) (emphasis in the original). Applicant herein submits the prior art of record fails to provide any such suggestion or incentive, either explicitly or implicitly. (It is recognized that the prior art need not have express written motivation to combine. Ruiz vs. A.B. Chance Co., 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004).)

Original Claims 1-4, 6-21 and 24-28 were rejected as obvious over EP, CN 1141279 and Mehta in view of O'Donnell and Branly et al. These rejections are respectfully traversed. The Examiner acknowledged that the abstracts of EP and CN 1141279 do not teach decontamination of animal manure. However, the Examiner errs in characterizing Mehta as teaching "combining organic fertilizers with microorganisms,...and recognizing that manure is an organic fertilizer". As discussed above, it is clear that a fair reading of Mehta would have motivated one of ordinary skill



in the art to *avoid* animal manures as they (according to Mehta) contribute an undesirable amount of toxic chemicals and/or toxic metals to the soils on which they are used. In fact Mehta's organic fertilizer component is selected from items that are *not* animal manure: "processed animal body and vegetable products such as blood meal, cottonseed meal, ocean kelp meal, fish fertilizers such as fish emulsion, feather meal, and the like." (Mehta at column 2, lines 37-45.) In any case, Mehta does not teach or suggest decontaminating these materials, nor any motivation or incentive to do so.

The Examiner uses O'Donnell and Branly et al. for the teaching of the use of *Bacillus* microorganisms, and then concludes that "it would have been obvious to optimize within the teachings of these three references [apparently the primary references] and pick *Bacillus* species that are advantageous over the others for use in soil treatment ...to find the right amount for use in a soil treatment with fertilizers would have been obvious to one of ordinary skill in the art at the time the invention was made."

Firstly, the critical conception and discovery of the inventor of the present application is that the combination of decontaminated manure with select *Bacillus* species (or combination of select *Bacillus* species) that produce stable spores in a certain purity produce a fertilizer composition which has a high concentration of beneficial *Bacilli* and which is effective for increasing crop yields, or maintaining crop yields with less fertilizer. See page 15, lines 1-23, especially lines 7-8. Independent claim 24 puts this in functional terms, and also recites humic acid as a required ingredient, primarily as it helps to increase the hardness of the solid fertilizer embodiments of the inventive compositions.

While the Examiner finds that "it would have been obvious to optimize within the teachings of these three references [apparently the primary references] and pick *Bacillus* species that are advantageous over the others for use in soil treatment ...[and] to find the right amount for use in a soil treatment", the sole support for this conclusion was the presence in separate prior patent documents of the individual elements.

As held in Panduit Corp. vs. Dennison Manufacturing, 1 USPQ2d 1593, 1605 (Fed. Cir. 1987):

A holding of invalidity on that basis . . . is contrary to statute and would defeat the congressional purpose in enacting Title 35. Indeed, that the elements noted by the court lay about in the prior art available for years to

all skilled workers, without, as the court found, suggesting anything like the claimed inventions, is itself evidence of nonobviousness.

In some cases, as pointed out above, the prior patent document teaches away from (or leads away from) the use of decontaminated manure. “The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention.” In re Mercier, 185 USPQ 774, 778, CCPA 1975.

The board’s approach amounts, in substance, to nothing more than a hindsight “reconstruction” of the claimed invention by relying on isolated teachings of the prior art without considering the over-all context within which those teachings are presented. Without the benefit of appellant’s disclosure, a person having ordinary skill in the art would not know what portions of the disclosure of the reference to consider and what portions to disregard as irrelevant, or misleading. *Id.* at 1975.

Secondly, regarding the amount of *Bacillus* to use, after the conception of the invention, certainly some experimental optimization is involved in preparing the *Bacillus* spores in the concentrations claimed; however, the procedures used to grow *Bacillus* spores are readily known, as acknowledged by the inventor on page 33, lines 6 to page 34, line 12, and Applicant does not agree that it would have been obvious to optimize obvious variations within the teaching of the references. “Routine experimentation” and “optimization” do not negative patentability. Many tests are of necessity “routine” yet they must be guided and directed as to eliminate areas of speculation. In re Fay and Fox, 146 USPQ 47; 35 USC Section 103(a), last sentence.

Claims 5, 8, 22-23 were rejected as obvious over the same references as above, and further in view of Johnson et al., Moran et al., and Robinson. Claim 5 recites that the composition is formed into prills or pellets. Claim 8 recites that the humic acid component of claim 2 is derived from lignite; Claim 22 recites that the humic acid is derived from Leonardite; and Claim 23 recites that the humic acid is potassium humate.

Claims 11-12 were rejected as obvious over EP, CN 1141279, and Mehta in view of O'Donnell and Branly et al., and further in view of Wilson and Lamy et al. Claim 11 depends directly from Claim 1 and recites that the decontaminated manure is derived from reaction of raw manure with concentrated mineral acid and subsequently dried. Claim 12 also depends directly from claim 1 and recites that the decontaminated manure is derived from reaction of raw manure with a hypochlorite compound and subsequently dried.

These rejections are respectfully traversed. The remarks herein above regarding the rejection of Claims 1-4, 6-21 and 24-28 over the combination of cited references are equally applicable to the rejections of Claims 5, 8, 22-23, and 11-12, all of which depend from Claim 1, some with intervening claims. While not admitting that these features would have been obvious to a person having ordinary skill in the art at the time the invention was made, even if so it is axiomatic patent law that claims dependent from nonobvious claims may add obvious components or elements. As Applicant maintains that Claim 1, as amended, is patentable, it is maintained that Claims 5, 8, 22-23, and 11-12 are also patentable, and these rejections are respectfully traversed.

Appln. No. 10/038,676  
Amdmt. dated October 14, 2004  
Reply to Office Action of August 11, 2004

**Conclusion**

Given the above claim amendments and the comments regarding the references cited by the Examiner, it is now respectfully submitted that all pending claims are now in condition for allowance, which is earnestly solicited. However, should the Examiner have further objections, rejections, or comments to bring the case to conclusion, the Examiner is cordially requested to contact the undersigned prior to further rejection.

Respectfully submitted,



Jeffrey L. Wendt  
Reg. No. 32,952

October 14, 2004  
Jeffrey L. Wendt, Esq.  
34 DriftOak Circle  
The Woodlands, TX 77381

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